## What We Claim Is:

1. A method for the prophylaxis or treatment of a hyperlipidemic condition or disorder in a subject which comprises administering a first amount of an apical sodium co-dependent bile acid transporter inhibitor and a second amount of an HMG Co-A reductase inhibitor wherein:

the apical sodium co-dependent bile acid transporter inhibitor is selected from the group consisting of:

$$H_3$$
CO

 $OCH_3$ 
 $OCH_3$ 
 $OCH_3$ 
 $OCH_3$ 
 $OCH_3$ 
 $OCH_3$ 
 $OCH_3$ 
 $OCH_3$ 
 $OCH_3$ 
 $OCH_3$ 

HOSS

effective amount of said inhibitors.

5

10

;
and the pharmaceutically acceptable salts, esters, and prodrugs thereof; and
the first and second amounts of said inhibitors together comprise a therapeutically

or a pharmaceutically acceptable salt, ester or prodrug thereof.

3. The method of Claim 1 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

5. The method of Claim 1 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

6. The method of Claim 1 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

7. The method of Claim 1 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

- 5 or a pharmaceutically acceptable salt, ester or prodrug thereof.
  - 8. The method of Claim 1 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

10

or a pharmaceutically acceptable salt, ester or prodrug thereof.

10. The method of Claim 1 wherein the apical sodium co-dependent bile acid
 transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

12. The method of Claim 1 wherein the apical sodium co-dependent bile acid
 transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

or a pharmaceutically acceptable salt, ester or prodrug thereof.

14. The method of Claim 1 wherein the apical sodium co-dependent bile acid
 transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

15. The method of Claim 1 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

16. The method of Claim 1 wherein the HMG Co-A reductase inhibitor is selected from the group consisting of mevastatin, lovastatin, simvastatin, pravastatin, fluvastatin, cerivastatin, atorvastatin, ZD-4522, and the pharmaceutically acceptable salts, esters, conjugate acids, and prodrugs thereof.

5

17. The method of Claim 1 wherein the HMG Co-A reductase inhibitor is selected from the group consisting of atorvastatin, simvastatin, pravastatin, ZD-4522, and the pharmaceutically acceptable salts, esters, conjugate acids, and prodrugs thereof.

10

18. The method of Claim 1 wherein the HMG Co-A reductase inhibitor comprises mevastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.

15

- 19. The method of Claim 1 wherein the HMG Co-A reductase inhibitor comprises atorvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 20. The method of Claim 1 wherein the HMG Co-A reductase inhibitor comprises simvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 21. The method of Claim 1 wherein the HMG Co-A reductase inhibitor comprises pravastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
  - 22. The method of Claim 1 wherein the HMG Co-A reductase inhibitor comprises lovastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 25
- 23. The method of Claim 1 wherein the HMG Co-A reductase inhibitor comprises cerivastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 24. The method of Claim 1 wherein the HMG Co-A reductase inhibitor comprises fluvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.

ائي. د ولاد الوقع وقع الذات العالم والإنجازة الإن الحفقية.

- 25. The method of Claim 1 wherein the HMG Co-A reductase inhibitor comprises ZD-4522, or a pharmaceutically acceptable salt, ester, conjugate acid, or prodrug thereof.
- 26. The method of Claim 1 wherein the HMG Co-A reductase inhibitor comprises
   NK-104, or a pharmaceutically acceptable salt, ester, conjugate acid, or prodrug thereof.
  - 27. The method of Claim 1 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

the HMG Co-A reductase inhibitor is selected from the group consisting of mevastatin, lovastatin, simvastatin, pravastatin, fluvastatin, cerivastatin, atorvastatin, ZD-4522, NK-104, and the pharmaceutically acceptable salts, esters, conjugate acids, and prodrugs thereof.

15

28. The method of Claim 27 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises the 4R,5R enantiomer of

10

15

20

or a pharmaceutically acceptable salt, ester or prodrug thereof.

29. The method of Claim 27 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises the racemate of

or a pharmaceutically acceptable salt, ester or prodrug thereof.

- 30. The method of Claim 28 wherein the HMG Co-A reductase inhibitor is selected from the group consisting of atorvastatin, simvastatin, pravastatin, ZD-4522, and the pharmaceutically acceptable salts, esters, conjugate acids, and prodrugs thereof.
- 31. The method of Claim 28 wherein the HMG Co-A reductase inhibitor comprises mevastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 32. The method of Claim 28 wherein the HMG Co-A reductase inhibitor comprises lovastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
  - 33. The method of Claim 28 wherein the HMG Co-A reductase inhibitor comprises simvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
  - 34. The method of Claim 28 wherein the HMG Co-A reductase inhibitor comprises pravastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 35. The method of Claim 28 wherein the HMG Co-A reductase inhibitor comprises fluvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.

10

15

25

30

- 36. The method of Claim 28 wherein the HMG Co-A reductase inhibitor comprises cerivastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 37. The method of Claim 28 wherein the HMG Co-A reductase inhibitor comprises atorvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 38. The method of Claim 28 wherein the HMG Co-A reductase inhibitor comprises ZD-4522, or a pharmaceutically acceptable salt, ester, conjugate acid, or prodrug thereof.
- 39. The method of Claim 28 wherein the HMG Co-A reductase inhibitor comprises NK-104, or a pharmaceutically acceptable salt, ester, conjugate acid, or prodrug thereof.
- 40. The method of Claim 28 wherein the apical sodium co-dependent bile acid transporter inhibitor and the HMG Co-A reductase inhibitor are administered in a sequential manner.
- 41. The method of Claim 28 wherein the apical sodium co-dependent bile acid transporter inhibitor and the HMG Co-A reductase inhibitor are administered in a substantially simultaneous manner.
  - 42. The method of Claim 28 wherein the weight ratio of apical sodium codependent bile acid transporter inhibitor to HMG Co-A reductase inhibitor administered is between about 1:50 to about 3:1.
    - 43. The method of Claim 28 wherein said apical sodium co-dependent bile acid transporter inhibitor is administered in a daily dose ranging from about 0.008 mg to about 100 mg, and said HMG Co-A reductase inhibitor is administered in a daily dose ranging from about 0.05 mg to about 100 mg.

and the contract of the contra

44. The method of Claim 28 wherein said apical sodium co-dependent bile acid transporter inhibitor is administered in a daily dose range from about 0.08 mg to about 100 mg.

5

- 45. The method of Claim 28 wherein the HMG Co-A reductase inhibitor is administered in a daily dose range from about 0.05 mg to about 100 mg.
- 46. A composition comprising a first amount of an apical sodium co-dependent bile acid transporter inhibitor selected from the group consisting of

10

and the pharmaceutically acceptable salts, esters and prodrugs thereof;

a second amount of the HMG Co-A reductase inhibitor, or a pharmaceutically acceptable salt, ester, conjugate acid, or prodrug thereof; and

a pharmaceutically acceptable carrier;

wherein the first and second amounts of said inhibitors together comprise a therapeutically effective amount of said inhibitors.

47. The composition of Claim 46 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

- 5 or a pharmaceutically acceptable salt, ester or prodrug thereof.
  - 48. The composition of Claim 46 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

10

or a pharmaceutically acceptable salt, ester or prodrug thereof.

50. The composition of Claim 46 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

51. The composition of Claim 46 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

52. The composition of Claim 46 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

- 5 or a pharmaceutically acceptable salt, ester or prodrug thereof.
  - 53. The composition of Claim 46 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

10

or a pharmaceutically acceptable salt, ester or prodrug thereof.

55. The composition of Claim 46 wherein the apical sodium co-dependent bile
 acid transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

10

or a pharmaceutically acceptable salt, ester or prodrug thereof.

57. The composition of Claim 46 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

58. The composition of Claim 46 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

60. The composition of Claim 46 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises

or a pharmaceutically acceptable salt, ester or prodrug thereof.

- 61. The composition of Claim 46 wherein the HMG Co-A reductase inhibitor is selected from the group consisting of mevastatin, lovastatin, simvastatin, pravastatin, fluvastatin, cerivastatin, atorvastatin, ZD-4522, NK-104, and the pharmaceutically acceptable salts, esters, conjugate acids, and prodrugs thereof.
  - 62. The composition of Claim 46 wherein the HMG Co-A reductase inhibitor is selected from the group consisting of atorvastatin, simvastatin, pravastatin, ZD-4522, and the pharmaceutically acceptable salts, esters, conjugate acids, and prodrugs thereof.
    - 63. The composition of Claim 46 wherein the HMG Co-A reductase inhibitor comprises mevastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.

15

- 64. The composition of Claim 46 wherein the HMG Co-A reductase inhibitor comprises atorvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 65. The composition of Claim 46 wherein the HMG Co-A reductase inhibitor comprises simvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
  - 66. The composition of Claim 46 wherein the HMG Co-A reductase inhibitor comprises pravastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 10 67. The composition of Claim 46 wherein the HMG Co-A reductase inhibitor comprises lovastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
  - 68. The composition of Claim 46 wherein the HMG Co-A reductase inhibitor comprises cerivastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
  - 69. The composition of Claim 46 wherein the HMG Co-A reductase inhibitor comprises fluvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 70. The composition of Claim 46 wherein the HMG Co-A reductase inhibitor comprises ZD-4522, or a pharmaceutically acceptable salt, ester, conjugate acid, or prodrug thereof.
  - 71. The composition of Claim 46 wherein the HMG Co-A reductase inhibitor comprises NK-104, or a pharmaceutically acceptable salt, ester, conjugate acid, or prodrug thereof.
  - 72. The composition of Claim 46 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises the racemate of

10

15

or a pharmaceutically acceptable salt, ester or prodrug thereof; and

the HMG Co-A reductase inhibitor is selected from the group consisting of mevastatin, lovastatin, simvastatin, pravastatin, fluvastatin, cerivastatin, atorvastatin, ZD-4522, NK-104, and the pharmaceutically acceptable salts, esters, conjugate acids, and prodrugs thereof.

73. The composition of Claim 46 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises the 4R,5R enantiomer of

or a pharmaceutically acceptable salt, ester or prodrug thereof; and

the HMG Co-A reductase inhibitor is selected from the group consisting of mevastatin, lovastatin, simvastatin, pravastatin, fluvastatin, cerivastatin, atorvastatin, ZD-4522, NK-104, and the pharmaceutically acceptable salts, esters, conjugate acids, and prodrugs thereof.

74. The composition of Claim 73 wherein the HMG Co-A reductase inhibitor is selected from the group consisting of atorvastatin, simvastatin, pravastatin, ZD-4522, NK-104, and the pharmaceutically acceptable salts, esters, conjugate acids, and prodrugs thereof.

5

- 75. The composition of Claim 73 wherein the HMG Co-A reductase inhibitor comprises mevastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 76. The composition of Claim 73 wherein the HMG Co-A reductase inhibitor comprises lovastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
  - 77. The composition of Claim 73 wherein the HMG Co-A reductase inhibitor comprises simvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.

15

78. The composition of Claim 73 wherein the HMG Co-A reductase inhibitor comprises pravastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.

- 79. The composition of Claim 73 wherein the HMG Co-A reductase inhibitor comprises fluvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 80. The composition of Claim 73 wherein the HMG Co-A reductase inhibitor comprises cerivastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
- 81. The composition of Claim 73 wherein the HMG Co-A reductase inhibitor comprises atorvastatin, or a pharmaceutically acceptable salt, ester or prodrug thereof.
  - 82. The composition of Claim 73 wherein the HMG Co-A reductase inhibitor comprises ZD-4522, or a pharmaceutically acceptable salt, ester, conjugate acid, or prodrug thereof.

- 83. The composition of Claim 73 wherein the HMG Co-A reductase inhibitor comprises NK-104, or a pharmaceutically acceptable salt, ester, conjugate acid, or prodrug thereof.
- 84. The composition of Claim 73 wherein the weight ratio of apical sodium codependent bile acid transporter inhibitor to HMG Co-A reductase inhibitor is between about 1:50 to about 3:1.
- 85. A kit containing a first dosage form comprising an ASBT inhibitor and a second dosage form comprising an HMG Co-A reductase inhibitor, wherein the apical sodium co-dependent bile acid transporter inhibitor is selected from the group consisting of:

and the pharmaceutically acceptable salts, esters and prodrugs thereof.

86. A kit of Claim 85 wherein the apical sodium co-dependent bile acid transporter inhibitor comprises the 4R,5R enantiomer of

- 87. A kit of Claim 86 wherein the HMG Co-A reductase inhibitor is selected from the group consisting of mevastatin, lovastatin, simvastatin, pravastatin, fluvastatin, cerivastatin, atorvastatin, ZD-4522, NK-104, and the pharmaceutically acceptable salts, esters, conjugate acids, and prodrugs thereof.
- 88. A kit of Claim 86 wherein the HMG Co-A reductase inhibitor is selected from the group consisting of atorvastatin, simvastatin, pravastatin, ZD-4522, and the pharmaceutically acceptable salts, esters, conjugate acids, and prodrugs thereof.
  - 89. The compound having the formula

and the pharmaceutically acceptable salts, esters and prodrugs thereof.